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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/564,769 | 06/12/2006 | Daria Onichtchouk | WEICKM-53 | 9878 |

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| EXAMINER | |
|---|---|
| NGUYEN, QUANG | |

| ART UNIT | PAPER NUMBER |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/564,769 | ONICHTCHOUK ET AL. | |
| | Examiner | Art Unit | |
| | QUANG NGUYEN, Ph.D. | 1633 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *40-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *40-62* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Claims 40-62 are pending in the present application, and they are subjected to the following restrictions.

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claims 40, 44, 47-49 and 62, drawn to a pharmaceutical composition comprising **a DG001 protein and/or a functional fragment thereof**; and a kit comprising the same.

Group 2, claims 40-45, 47-49 and 62, drawn to a pharmaceutical composition comprising **a nucleic acid molecule encoding a DG001 protein and/or a functional fragment thereof**; and a kit comprising the same.

Group 3, claims 40-49 and 62, drawn to a pharmaceutical composition comprising **an effector/modulator (e.g., antisense, aptamer...) of a nucleic acid molecule encoding a DG001** protein and/or a functional fragment thereof; and a kit comprising the same.

Group 4, claims 40, 44, 47-49 and 62, drawn to a pharmaceutical composition comprising **an effector/modulator (e.g., antibody or small chemical molecule) of a DG001 protein and/or a functional fragment thereof**; and a kit comprising the same.

Group 5, claim 52, drawn to **a non-human transgenic animal** exhibiting a modified expression of a DG001 polypeptide, **wherein the expression of the DG001 polypeptide is increased**.

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Group 6, claim 52, drawn to a **non-human transgenic animal** exhibiting a modified expression of a DG001 polypeptide, **wherein the expression of the DG001 polypeptide is reduced**.

Group 7, claim 53, drawn to **a recombinant host cell exhibiting an increased expression of a DG001 polypeptide**.

Group 8, claims 53 and 62, drawn to **a recombinant host cell exhibiting a reduced expression of a DG001 polypeptide**; and a kit comprising the same host cell..

Group 9, claim 54, drawn to **a method of identifying a (poly)peptide involved in the regulation of energy homeostasis and/or metabolism in a mammal comprising the recited steps in claim 54**.

Group 10, claim 55, drawn to **a method of screening an agent which effects/modulates the interaction of a DG001 polypeptide with a binding target comprising the recited steps in claim 55**.

Group 11, claim 56, drawn to a method of screening an agent which effects/modulates the activity of a **DG001 polypeptide comprising the recited steps in claim 56**.

Group 12, claim 60, drawn to **a method for increasing insulin production in a cell comprising stimulating DG001 expression in said cell by introducing DG001 into said cell**.

Group 13, claim 60, drawn to **a method for increasing insulin production in a cell comprising stimulating DG001 expression in said cell by introducing a DG001 effector/modulator into said cell**.

Group 14, claim 61, drawn to a cell preparation obtained by the method of claim 60.

It is noted that **claims 50-51 and 57-59 are USE claims** without any reciting method steps; therefore it is unclear whether Applicants intend to claim compositions or methods. Should Applicants intend to claim compositions, they will be grouped accordingly to the above restricted composition groups. **Should Applicants intend to claim methods, they will be restricted according to amended method steps to be recited**.

The technical feature linking at least Groups 1-14 appears to be that they all relate to a DG001 which corresponds to human pleiotrophin.

However at the effective filing date of the present application (7/16/2003), at least Colley (WO 99/53943; IDS) already disclosed pharmaceutical compositions comprising pleiotrophin or a nucleic acid encoding pleiotrophin for treating a human or an animal in need thereof. Additionally, Wellstein et al (WO 00/20869; IDS) also disclosed a kit for measuring pleiotrophin in samples and for diagnosing pleiotrophin-positive diseases.

Therefore, the technical feature linking the inventions of at least Groups 1-14 does not constitute a special technical feature a defined by PCT Rule 13.2, as it does not differentiate the claimed subject matter a whole over the prior art. Since according to Rule 13.2 PCT the presence of such a common or corresponding special technical feature is an absolute prerequisite for unity to be established, and given that there does not appear to be any other technical feature common to the claimed subject matter as a whole which might be able to fulfill this role, the currently claimed subject matter lacks unity of invention according to Rule 13.1 PCT.

Consequently, the claimed subject matter is restricted into the above Groups of Inventions for the following reasons.

Inventions 1-8 and 14 are directed to compositions that are different chemically, structurally and properties one from the others. For example, a DG001 protein of Group 1 is made up of amino acid residues; a nucleic acid encoding a DG001 protein of Group 2 is composed of nucleotides; an effector/modulator of Group 3 (e.g., an anti-sense oligonucleotide, antisense vector; an aptamer) does not encode a DG001 protein; an

effector/modulator of Group 4 (e.g., an antibody or a small chemical molecule) does not have the same structure or properties as those of a DG001 protein; a non-human transgenic animal in Group 5 has mutually exclusive characteristics (e.g., increased DG001 polypeptide expression) from a non-human transgenic animal of Group 6 (e.g., reduced DG001 polypeptide expression) and both are physically different from recombinant host cells of Groups 7-8 or a cell preparation of Group 14. Similarly, recombinant host cells of Groups 7-8 have mutually exclusive characteristics one from the other; and unlike the cell preparation of Group 14 they do not have to express insulin as required by the composition of Group 14.

Inventions 9-13 are drawn to methods with different method steps and starting materials, as well as different desired end-results. Unlike the methods in Groups 9-11 which are different screening methods, the methods in Groups 12-13 are directed to methods for increasing insulin production in a cell using DG001 and effector/modulator of DG001, respectively.

Inventions 1 and anyone of the methods in Groups 9-12 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the composition of Group 1 can be used to in anyone of the different methods in Groups 9-12; or alternatively the composition of Group 1 can be used to generate specific antibodies.

Inventions 4 and the method in Group 13 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the composition of Group 4 can be used at least in a therapy method or in a screening method.

Inventions 12-13 and Invention 14 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the cell preparation in Group 14 can be prepared at least by anyone of the two different methods in Groups 12-13.

Because the currently claimed subject matter lacks unity according to Rule 13.1 PCT for the reasons set forth above, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a

matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

***Species restriction:***

***Should Applicants elect Group 3***, this application contains claims directed to **more than one species of an effector/modulator of a nucleic acid encoding a DG001 protein**. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

***(a) an anti-sense oligonucleotide; and (b) an aptamer.***

The following claims are generic: at least claims 40 and 62.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Each of the above listed effector/modulator of a nucleic acid encoding a DG001 protein is different one from the other because each has different structure and properties one from the other. Therefore, each different structure can be considered to be a "special technical feature" and therefore the above listed effector/modulators of a nucleic acid encoding a DG001 protein lack the same or corresponding special technical features.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Joseph T. Woitach, Ph.D., may be reached at (571) 272-0739.

**To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.**

**Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.**

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

/QUANG NGUYEN/
Primary Examiner, Art Unit 1633